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The Saga of Food Supplements: Safety and Missing Knowledge – A Commentary

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Food supplements, including herbal and dietary, constitute one of the fastest growing industries with expenditures reaching worldwide \$60 billion annually. Sales of herbal dietary supplements in the United States increased by 7.9% in 2013, reaching a total estimated figure of six billion dollars (Lindstrom et al., 2014). These sales account for approximately 20% of the overall drug market (Kirk and Dunker, 2014). The use of herbal supplements increased 20 times in the last 25 years, counting in 2013 with ~ 50% of the USA adult population as consumers (Bailey et al., 2013). Yet, while the appetite of consumers for supplements continues to increase, regulatory safety guidelines and the knowledge of their effects are lacking.

Perhaps change is in the air. An uproar was raised after the investigation results of the New York State Attorney General's office were reported in New York Times February 3, 2015 (Assoc. Press, 2015). Accusations that herbal supplements do not contain the listed ingredients prompted major retailers, including Walgreens, Wal-Mart, GNC, and Target, to stop selling several herbal supplements, including some store brands of ginseng (*Panax trifolius*), ginkgo (*Ginkgo biloba*), echinacea (*Echinacea* spp.) and St. John's wort (*Hypericum perforatum*). These herbal supplements contained some plant components, including carrot powder, but no principal active compounds responsible for the alleged beneficial effects were detected.

Our team has been investigating the molecular mechanisms of plant flavonoids in health using several model systems during the past few years. Apigenin, a flavonoid abundant in celery and parsley, two vegetables that are quite common in the Mediterranean diet, is emerging as a promising anti-cancer and immune-regulatory molecule (Shukla and Gupta., 2010). Our studies have shown that apigenin and diets rich in apigenin induce apoptosis in cancer cells, alter cancer proliferative gene expression, re-duce inflammation and restore normal metabolic function (Nahomi et al., 2013). Yet, the effects of supplements containing apigenin have not been studied.

As part of our efforts to investigate the mechanisms responsible for the beneficial health effects of dietary compounds, the content of apigenin was studied in several herbal supplements, using commonly accepted analytical assessments (Figure 1). In agreement with the observations of the New York State Attorney General's Office, we noted several label discrepancies in the reported amounts and contents, highlighting the inconsistencies between label claims and supplement contents.

In the past few years, several incidents in which label discrepancies have been reported, highlighting the need for greater government oversight. Dietary supplements in USA are regulated by The U.S. Food and Drug Administration (FDA), but under a different set of guidelines than those covering

“classical” foods and drugs. Based on the Dietary Supplement Health and Education Act of 1994, supplement makers, unlike manufacturers for conventional drugs, are exempt from demonstrating that their products are safe or effective. The only requirement is to report accurate and truthful labels. If the FDA becomes aware of an unsafe supplement being marketed, they may request a warning be included on the label or the product be removed from the market.

The regulations for dietary supplements should be framed to ensure that consumers are protected and that the product is effective. The need for revised guidelines is becoming even more relevant considering that 45-50% of the USA adult population, ~16.4% of adolescents, and ~7 to 10.7% of children ages 5-11 consume herbal supplements (Bailey et al., 2013). Racial, cultural and socio-economical differences in consumption have been reported. Approximately 50% of Native Americans and 43% of whites use supplements and increased use has been associated with higher income (Barnes et al., 2008). Supplements classified as non-mineral and non-vitamin are used by 18% of adults (Barnes et al., 2008). Fish oil (omega 3) has been reported as the most common supplement consumed in the United States (Barnes et al., 2004; Barnes, 2008), yet the efficacy of this supplement remains unknown.

Considered alternative medicines, herbal supplements are thus commonly combined with other prescription medicines. Of supplement consumers, 72% also use prescription medications and 84% have consumed an over-the counter medication in the prior 12 months (Gardiner et al., 2007). Remarkably, a report published in 2007, indicates that most medical doctors were unaware that dietary supplements are subject to different FDA regulations than foods or prescription medicines (Ashar, et al., 2007). Clinically serious interactions between prescription drugs and supplements have been noted in several reports (Kaufman et al., 2002; Ernst, 2000; Mills et al., 2004; Sorensen, 2002; Valli and Giardina, 2002). Yet, any clinical studies that evaluate the effects of supplements in combination with other drugs are, missing.

Surveys indicate that approximately 19% of the USA population have used herbs for health conditions, such as head or chest cold, a musculoskeletal condition, stomach or intestinal illness, anxiety/depression, insomnia, severe headache or migraine, menopause, cholesterol, and recurring pain (Barnes, et al., 2004; Gardiner et al., 2007; Tindle et al., 2005; Ni et al., 2002; Fennell, 2004; Graham et al., 2005). The consumer needs a better understanding and evidence on the benefits, and risks, associated with supplements.

The lack of quality control of herbal compounds at the manufacturer level is a serious concern in that the therapeutic effects of the compounds are frequently overstated. While central control features related to security and composition can be obtained through useful and accepted analytical approaches, little has been done. Regrettably, such controls are still greatly needed.

In recent years, the availability of publications of scientific data has been rapidly increasing, but dietary studies using supplements alone or in combination are scarce. To bring the true effects of supplements to clinical and public view, an increased sponsorship of clinical studies is very much needed. Moreover, supplemental nutrition and herbal medicine should be prescribed by certified professionals rather than by a free and misinformed market. Urgent changes are needed to: 1) to update the regulations on supplements and establish clear safety guidelines for consumers; 2) to gain a better understanding of the mechanisms of supplement actions and effects; and 3) to determine and evaluate the possible interactions of supplements with drugs.

As consumer demand for supplements continues to increase, limited funding for research and outdated safety guidelines are alarming. More and better information on supplements is needed. Yet, any analytical studies on supplements will apparently continue to be delayed due to a government, paralyzed by lobbyists and lack funding, continues to avoid the real question: as to whether supplements are really safe and effective?

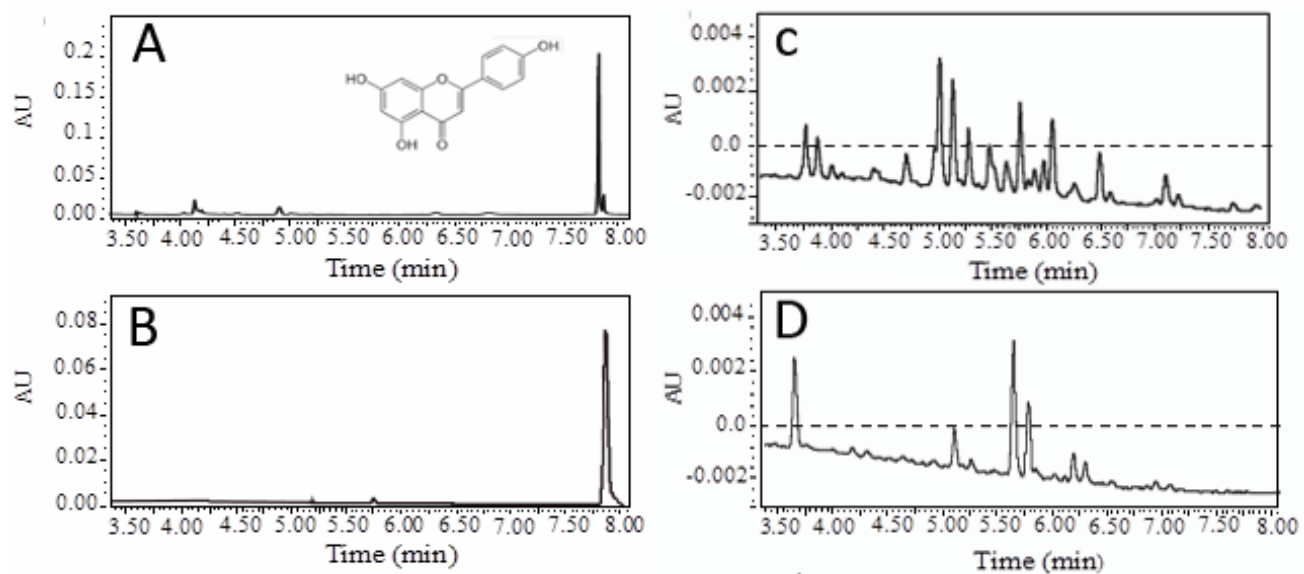


Figure 1. Content of apigenin in different supplements.

Fig. 1A is apigenin standard obtained from Sigma-Aldrich, Inc.

Fig. 1B is content of apigenin per capsule was 9.73 mg whereas label indicates 50 mg/capsule.

Fig. 1C & Fig 1D are chromatograms of two other supplements from different manufacturers, but expected flavonoids were not detected.

Note: For analysis, ten supplement capsules were extracted three times with 70% methanol, filtered through a 0.2 μ M membrane, and 20 μ L of each sample was injected into a Waters 2695 separation module with a 2996 detector W2690-5 Symmetry C18 column (3.5 μ m, 4.6 x 75 mm) and subsequently analyzed using Empower software (Waters Corp., Milford, MA). Concentrations were measured at 340 nm corresponding to the absorbance wavelength for apigenin.

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